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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/603,131	06/23/2000	Bethany A. Janowski	UTSD:578USC2/RAN	3524

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EXAMINER

PAK, MICHAEL D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 02/10/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 09/603,131	Applicant(s) JANOWSKI ET AL.	
	Examiner Michael Pak	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-5, 7-8, 17-18, 22-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Respons to Amendment

1. The amendments filed 8 October 2002 (Paper No. 11) has been entered. Claims 2, 3, 6, and 19 have cancelled. Claims 1, 4-5, 7-8, 17-18, and 22-23 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed 8 October 2002 (Paper No. 11) have been fully considered but they are not found persuasive.

Claim Rejections - 35 USC § 112

4. Claims 1, 4-5, 7-8, 17-18, and 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "LXR α expression construct" which is not defined or limited in terms of structure and the metes and bounds are unclear. Claim 3 recite Markush groups of names directed to LXR α constructs without structure and the metes and bounds are unclear. Claims 4-5, 7-8, 17-18, and 22-23 are dependent on claim 1. Applicants argue that one of skilled in the art would have been well apprised of what this term meant at the time the present application was filed because Willy et al. paper was published and the filed was regularly using the term as in Leblanc et al. However,

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Willy et al. disclose a specific species of LXR α and the function of the LXR α is in relation to RXR interaction and the specification does not indicate that the LXR α claim limitation is drawn to the same species. Rather it appears to be a genus of polypeptide which interacts with oxysterol which includes alleles from different species and homologues and analogues whose structure is not known can be envisioned. The reference Lebanc et al. was not cited in the IDS nor reference made of record by the examiner and the reference was not submitted by the applicant for review.

Claim 1 recites the limitation "LXR α protein" which is not defined or limited in terms of structure and the metes and bounds are unclear. Claims 4-5, 7-8, 17-18, and 22-23 are dependent on claim 1. Applicants again argue in a similar manner as above that one of skilled in the art would have been well apprised of what this term meant at the time the present application was filed because Willy et al. paper was published. However, Willy et al. disclose a specific species of LXR α and the function of the LXR α is in relation to RXR interaction and the specification does not indicate that the LXR α claim limitation is drawn to the same species. Rather it appears to be a genus of polypeptide which interacts with oxysterol which includes alleles from different species and homologues and analogues whose structure is not known can be envisioned.

Claim 1 recites the limitation "oxysterol activator" which is not defined or limited in terms of structure and the metes and bounds are unclear. Claims 4-5, 7-8, 17-18, and 22-23 are dependent on claim 1. Applicants argue that the term literally means "oxygenated sterols". However, the specification on page 4, lines 9-11, indicates that cholesterol and oxysterols are important for intermediates in several crucial biosynthetic

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pathways. Since cholesterol and many oxysterols are the biochemical material for biosynthesis of retinoids and ecdysteroids, it is not clear what the metes and bounds of what oxysterols are in light of applicants arguments under the 35 USC 102 rejections below that retinoids and ecdysteroids are not oxysterols.

5. Claims 1, 4-5, 7-8, 17-18, and 22-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed method using LXR α expression construct of examples 1-6 of the specification where the claim limitation clearly limits the structure of the construct, does not reasonably provide enablement for an LXR α construct where no structural limitations are provided in the claim. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The reasons for the rejection was set forth in the previous office action and reiterated below.

Claims encompass LXR α defined by function which is not defined in the specification. Thus, claims encompass mutants and variants of LXR α . However, the state of the art at the time of the invention was such that one skilled in the art did not know the ligand for the LXR α receptor of the specific species disclosed by Willy et al.(C29). Furthermore, even after the time of the invention, Lala et al.(C21; page 5, first paragraph, last line) teach that AF-2 domains are required for the specific species for function. One skilled in the art cannot make and use the scope of LXR α claimed

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because specific domains of the receptor are required for function such as the ligand binding domain, the DNA binding domain, the heterodimerization domain, and the activation domains, and each of these domains must act in concert with one another. It would require undue experimentation to make and use the full scope of the claimed invention.

Applicants argue that the claims do not encompass inoperable species and no issue of enablement is created. However, the basis for the rejection is the undue experimentation of using the method with the claimed LXR α receptor or construct which encompasses mutants, variants, and fragments that require functional domains without which the proteins cannot function as discussed above. Willy et al. disclose only a single receptor LXR α species and its interaction with RXR and does not discuss the genus of mutants, variants, or fragments of LXR α receptor encompassed by the claims.

Claim Rejections - 35 USC ' 102

6. Claims 1, 4-5, 7-8, 17-18, and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Willy et al. ((C29); Genes and Dev., 1995).

The reasons for the rejection has been set forth previously and reiterated below.

Willy et al. disclose the method of ligand screening with LXR α expressing host cell with a reporter construct (figures 4-7). The host cell is the CV-1 cell and luciferase activity is detected from the reporter (figure 4). Various candidate ligands are screened with the method (figure 4).

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The terms "LXR α expression construct", "LXR α protein", "oxysterol activator" are not defined or limited in terms of structure. Thus, Willy et al. methods encompass the claim limitations.

Applicants argue that retinoids used in the Willy et al. cannot be viewed as an oxysterol. However, the specification on page 4, lines 9-11, indicates that cholesterol and oxysterols are important for intermediates in several crucial biosynthetic pathways. Since cholesterol and many oxysterols are the biochemical material for biosynthesis of retinoids are encompassed by the term oxysterol. As discussed in the 35 USC 112, paragraph2, it is not clear what is the metes and bound of the term oxysterol activator.

7. Claims 1, 4-5, 7-8, 17-18, and 22-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Hogness et al. ((A); US 5,514,578).

The reason for the rejection has been set forth previously and reiterated below.

Hogness et al. disclose ecdysteroid receptor construct methods for screening ligand meeting the limitations of the claims (columns 6-20). Ecdysteroids are encompassed by the term oxysteroids because the specification does not define the term. Since ecdysteroids are oxysterols, the Hogness et al. ecdysteroid receptor is encompassed by the generic LXR α protein. The terms "LXR α expression construct", "LXR α protein", "oxysterol activator" are not defined or limited in terms of structure. Thus, Hogness et al. methods encompass the claim limitations.

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Applicants argue that Willy et al. defines what an LXR α expression construct and protein are. However, Willy et al. disclose only a single receptor LXR α species and its interaction with RXR and does not define what genus term "LXR α receptor" means.

8. No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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A handwritten signature in black ink, appearing to read "Michael Pak", written in a cursive style.

Michael Pak
Patent Examiner
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5 February 2003